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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,097	10/30/2003	Lotien Richard Huang	10434/60901	2657

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KENYON & KENYON LLP
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NEW YORK, NY 10004

EXAMINER

FICK, ANTHONY D

ART UNIT	PAPER NUMBER
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1753

MAIL DATE	DELIVERY MODE
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08/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/699,097

Applicant(s)

HUANG ET AL.

Examiner

Anthony Fick

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 27-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1 through 7, 9, 10, 13, 15 through 17, 19 through 22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Wiktorowicz et al. (U.S. 6,214,191).

With regards to all the claims, it is the examiner's position that applicant's use of the term "depth" within the claims corresponds to the height of the chamber or channel. Using applicant's figure 1 as an example, the depth of the reservoir is the distance between the top of the reservoir open to the environment and the bottom of the reservoir; the depth of the microfluidic channel is the distance between the top and bottom of the microfluidic channel.

Wiktorowicz discloses an integrated microfluidic device as seen in figures 3 and

- 4.

Regarding claim 1, the device comprises a microfluidic channel, 170, with an inlet and an outlet and a sample chamber, the sample chamber includes the compartments 130, 135, 132 and 160 inter-connected by the channel 180, comprising a first and

Art Unit: 1753

second electrode, 130a and 132a, capable of generating a first electric field within the sample chamber wherein the electric field transfers charged molecules in the sample chamber to the inlet of the channel. Figure 4 further shows a fluid reservoir, 140, connected to the sample chamber by the micro-fluidic channel and comprising a third electrode capable of generating a second electric field with at least the second electrode (column 15, paragraph 2). Figures 4 and 5 show the depth of the microfluidic channels, 170, corresponding to an amount cut into the bottom plate 120a. Figure 4 further shows a top plate 120a placed on top of the bottom plate to create the device. The top plate includes the compartments 130, 135 and 132 all cut out completely of the plate. Therefore in the finished device, the depth of the sample chamber, which includes compartments 130, 135 and 132, includes the same depth as the microfluidic channels (column 7, lines 8-14 and column 8, lines 6-29) as well as the additional depth provided by the compartments 130, 135, or 132. Since these compartments have a finite depth, the depth of the sample chamber must be greater than that of the microfluidic channel.

Regarding claim 5, Wiktorowicz further discloses the use of a polymer matrix material within the sample chamber to provide a pH gradient. The electric field elutes the charged molecules out of this polymer matrix.

Regarding claims 2 through 4, 6, 7, 9 and 10, Wiktorowicz discloses use of the device for several different samples (column 12, paragraphs 2 and 3).

Regarding claim 13, the device can contain a third electrode in the sample chamber, the dotted line in figure 3 (column 15, paragraph 2).

Regarding claim 15, the device can also be interpreted in an alternate view. Figures 3 and 4 also show the device comprises a microfluidic channel, 180, with an inlet and an outlet and a sample chamber, the sample chamber includes the compartments 135, 132, 160 and 140 inter-connected by the channels 170, comprising a first and second electrode, the electrode in 140 (column 15, paragraph 2) and 132a, capable of generating a first electric field within the sample chamber wherein the electric field transfers charged molecules in the sample chamber from the outlet of the channel. Figure 4 further shows a fluid reservoir, 130, connected to the sample chamber by the micro-fluidic channel and comprising a third electrode, 130a, capable of generating a second electric field with at least the second electrode. Figure 4 shows the depth of the microfluidic channel, 180, corresponding to an amount cut into the bottom plate 120a. Figure 4 further shows a top plate 120a placed on top of the bottom plate to create the device. The top plate includes the compartments 140, 135 and 132 all cut out completely of the plate. Therefore in the finished device, the depth of the sample chamber, which includes compartments 140, 135 and 132, includes the same depth as the microfluidic channel (column 7, lines 8-14 and column 8, lines 6-29) as well as the additional depth provided by the compartments 140, 135, or 132. Since these compartments have a finite depth, the depth of the sample chamber must be greater than that of the microfluidic channel.

Regarding claim 20, Wiktorowicz further discloses the use of a polymer matrix material within the sample chamber and the electric field transferring the molecules from the outlet of the channel and into the matrix material (column 16, paragraph 3).

Art Unit: 1753

Regarding claims 16, 17, 19, 21, 22 and 24, Wiktorowicz discloses use of the device for several different samples (column 12, paragraphs 2 and 3).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 8, 11, 12, 14, 18, 23, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiktorowicz as applied to claims 1 through 7, 9, 10, 13, 15 through 17, 19 through 22 and 24 above, and further in view of Adcock (U.S. 4,959,133).

The disclosure of Wiktorowicz is as stated above for claims 1 through 7, 9, 10, 13, 15 through 17, 19 through 22 and 24.

The differences between Wiktorowicz and the claims are the requirements of a specific matrix material, and inverted electric pulses.

Adcock teaches a method of field inversion electric pulses to force DNA or protein out of a gel and into an appropriate receiver (abstract). This method allows for the elution of higher molecular weights as in claims 8, 18 and 23.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the gel plugs and method of elution of Adcock within the device of Wiktorowicz because the plugs and method allow for elution of higher molecular weights in shorter times. Also agarose is a common material utilized for

Art Unit: 1753

electrophoresis and it would be obvious to use for the gel plugs as in claims 12 and 26. Because Wiktorowicz and Adcock are both concerned with electrophoretic separation products, one would have a reasonable expectation of success from the combination. Thus the combination meets the claims.

5. Claims 11, 12, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiktorowicz as applied to claims 1 through 7, 9, 10, 13, 15 through 17, 19 through 22 and 24 above, and further in view of Gautsch (U.S. 6,162,602).

The disclosure of Wiktorowicz is as stated above for claims 1 through 7, 9, 10, 13, 15 through 17, 19 through 22 and 24.

The difference between Wiktorowicz and the claims is the requirement of a specific matrix material.

Gautsch teaches an apparatus and method for nucleic acid base sequencing. Gautsch further teaches that capillary gel electrophoresis employing agarose or polyacrylamide gels is used to separate fragments (column 3, paragraph 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize agarose gels as in Gautsch within the device of Wiktorowicz because the agarose gel is an improved method over slab gel and agarose is a functional equivalent to the polyacrylamide utilized within Wiktorowicz (Gautsch column 3, paragraph 1). Because Wiktorowicz and Gautsch are concerned with separating fragments, one would have a reasonable expectation of success from the combination. Thus the combination meets the claims.

Response to Arguments

6. Applicant's arguments filed May 17, 2007 have been fully considered but they are not persuasive. Applicant argues that the reference to Wiktorowicz does not disclose the sample chamber comprising first and second electrodes of the presently claimed invention, specifically that the channels of Wiktorowicz do not provide a free flow of a fluid medium. Applicant also argues that separation channels will be recognized by those skilled in the art as not allowing the free flow of a fluid medium. The examiner respectfully disagrees. Applicant's characterization of separation channels is not accurate for every separation channel. The purpose of the channel is not to partially restrict the flow of a fluid medium as applicant states, but to restrict the motion of the desired molecular or particular materials being carried by a fluidic medium. Separation can occur without any restriction of fluid flow due to interactions with the species within the fluid. There are many free flow electrophoresis channels within the art that separate particles due to size, charge, etc. Second the claim requirements do not specify what fluid medium can flow freely in the channel. The velocity field of a flowing fluid varies greatly with the properties of the fluid, namely the density, viscosity, and the Reynolds number of the flow. While a specific environment may cause oil or molasses to be restricted in flow, water is able to freely flow through the same environment. Thus the choice of the fluid medium will alter whether it can flow freely or not. Third, the limitations of flowing fluid medium appear to be process limitations rather than structural limitations. In other words, a certain process may limit the fluid flow due to various forces that are applied during the process, but the actual structure allows free flow when

Art Unit: 1753

the process is not carried out. The channels of Wiktorowicz relied upon by the examiner, 180 and 170, are just straight channels with rectangular cross sections (see figures 3 through 5). The interactions of particles with the electric fields and the chemical species on the walls during the process of Wiktorowicz produce the required separations. However the structure matches applicant's own structure in figure 7, a straight channel with a rectangular cross section. The channels provide no hindrance, restriction or interference to a fluid medium and it is the examiner's position that the channels allow at least one fluid medium to flow freely.

Applicant also argues that the sample chamber of Wiktorowicz does not have a depth greater than the microfluidic channel depth. As stated above, figures 4 and 5 show the depth of the microfluidic channels, 170, corresponding to an amount cut into the bottom plate 120a. Figure 4 further shows a top plate 120a placed on top of the bottom plate to create the device. The top plate includes the compartments 130, 135 and 132 all cut out completely of the plate. Therefore in the finished device, the depth of the sample chamber, which includes compartments 130, 135 and 132, includes the same depth as the microfluidic channels (column 7, lines 8-14 and column 8, lines 6-29) as well as the additional depth provided by the compartments 130, 135, or 132. Since these compartments have a finite depth, the depth of the sample chamber must be greater than that of the microfluidic channel.

Applicant further argues the secondary references to Adcock and Gautsch do nothing to overcome the deficiencies of Wiktorowicz. It is the examiner's position that

Art Unit: 1753

Wiktorowicz does not have any deficiencies to overcome. Therefore the rejections are maintained.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

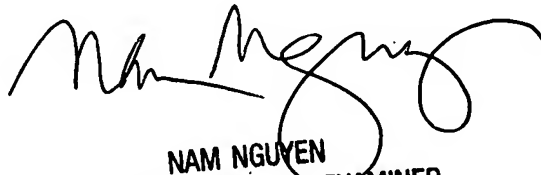
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony Fick whose telephone number is (571) 272-6393. The examiner can normally be reached on Monday - Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1753

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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AU 1753
August 3, 2007


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